MAR - 5 2001

GRAMS
American Suture, Inc.™

Summary of Safety & Effectiveness
Grams Polyester Nonabsorbable Suture

FDA Document Number

510K No. 003590

This summary is submitted in accordance with the Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR § 807.92. This summary demonstrates the equivalence of Grams American Sutures to those of the legally marketed devices listed.

A. Applicant:

Grams American Suture, Inc.
2225 Dakota Drive
Grafton, Wisconsin 53024 USA

B. Contact Person: A. J. Dimercurio

C. Date Prepared: November 16, 2000

D. Device Name:

- **Trade Name:** Grams Polyester Nonabsorbable Suture
- **Common Name:** Polyester Nonabsorbable Surgical Suture
- **Classification Name:** Nonabsorbable Poly (ethylene terephthalate) Surgical Suture

E. Predicate Devices:

- **Polyester Nonabsorbable Surgical Suture (CP Medical) 510K # K001172**
- **Polydek & Tevdek II, Polyester Nonabsorbable Surgical Suture (Genzyme Surgical Products) 510K # K990089**
- **Polyester Nonabsorbable Surgical Suture (ARC Medical Supplies) 510K # K000540**

F. Device Description:

Grams Polyester surgical suture is a nonabsorbable, sterile, surgical suture composed of Polyethylene terephthalate. It is prepared from fibers of high molecular weight, long-chain linear polyester having recurrent aromatic rings as an integral component. Suture characteristics include braided uncoated white (undyed) or green (D&C Green #6 dyed) and braided silicone coated (undyed) white or green (D&C Green #6 dyed).

G. Intended Use:

"Grams Polyester Nonabsorbable Suture is indicated for use in general, soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic and neurological procedures."

H. Technological Comparison to Predicated Devices:

Comparison Item	Grams American Suture Inc.	CP Medical	Genzyme Surgical Supply	ARC Medical Supplies
Suture Material is composed of Polyethylene terephthalate prepared from fibers of high molecular weight, long chain, linear polyesters having recurrent aromatic rings as an integral component	Same	Same	Same	Same
Suture material is offered undyed and dyed with the FDA listed colorant D&C #6 Green, per Title 21 CFR section 74.13206.	Same	Same	Same	Same
Suture Material is supplied uncoated and coated with a silicone coating to enhance its handling properties.	Same	Same	Same	Same
Suture Material is designed being a sterile, flexible, braided multifilament thread offered in a variety of lengths and a range of diameters with or without various needles attached.	Same	Same	Same	Same
Suture Material is Intended for Use in general soft tissue approximation and /or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	Same	Same	Same	Same
Suture Material meets or exceeds the performance requirements for "Nonabsorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia 23 and the current edition USP 24.	Same	Same	Same	Same

Technological Comparison to Predicated Device Continued:

Comparison Item	Grams American Suture Inc.	CP Medical	Genzyme Surgical Supply	ARC Medical Supplies
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Diameter" < 861 >	Same	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Tensile Strength" < 881 >	Same	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Needle Attachment" < 871 >	Same	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Suture Length Requirement"	Same	Same	Same	Same
Suture Material is packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR and USP XXIV.	Same	Same	Same	Same

I. Conclusion Statement of Equivalence:

Grams American Polyester Suture is composed of the same suture material, as are the predicated devices and the same design being a sterile, flexible, braided multifilament threads meeting all the requirements of the United States Pharmacopeia. The Grams American Polyester Suture is manufactured in the same manner as the predicate devices, being produced from long chain linear polyester having recurrent aromatic rings as an integral component and braided in operations considered standard in the fiber industry to form the suture fiber. The raw material manufacturer supplies to Grams American Suture the same suture materials as it supplies to other suture manufacturers including some (if not all) those listed above.

The results of data presented and of the testing demonstrate the substantial equivalence of Grams American Polyester Nonabsorbable Suture to that of the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Anthony J. Dimercurio
Vice President of Operations
Grams American Suture, Inc.
2225 Dakota Drive
Grafton, Wisconsin 53024

Re: K003590
Trade Name: Grams Polyester Nonabsorbable Suture
Regulatory Class: II
Product Code: GAT
Dated: November 16, 2000
Received: November 21, 2000

Dear Mr. Dimercurio:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GRAMS
American Suture, Inc.™

Intended Use Statement

"510(k) Notification"

21CFR 878. 5000 Nonabsorbable Poly (ethylene terephthalate) Surgical Suture

"Grams Polyester Nonabsorbable Suture is indicated for use in general, soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic and neurological procedures."

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003590

Prescription Use ✓
(Per 21 CFR 801.109)

K003590